Remarks of HENRY A. WAXMAN, Chairman,

Subcommittee on Health and the Environment before

The Council for Responsible Nutrition and Public Voice
January 28, 1986

I am delighted to be the luncheon speaker at this conference. I'm sure that the chef, knowing that this is a conference on food, must have worried late into the night about cooking for what is probably a group of very fussy eaters. I just hope that you are not equally fussy listeners.

I have been the chairman of the Health and Environment Subcommittee for 7 years now and I continue to marvel at the enormity of the issues with which we deal. We have authority over Medicare and Medicaid, over public health grant programs, over biomedical research and over health regulation. The latter jurisdiction includes the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Federal Centers for Disease Control (CDC) and a half dozen other agencies.

Working with these various organizations has reinforced a view that I have held for many years -- we cannot afford to treat diseases we can prevent. A dollar spent wisely on prevention invariably produces more benefits than a dollar spent on treatment and cure.

In this regard, I fear for this country if the budget cutters are ever able to attack the programs that feed the poor. The specter of substantial undernourishment is a frightening one. It takes no act of genius to know that one of the great benefits of food is that it prevents starvation.

But simply providing sustanance is not enough. It seems beyond doubt that good nutrition constitutes one of the most effective and desirable routes to disease prevention available to us today. Disseminating this message is what has drawn us all to this conference. Of course, as with most major policy matters, structuring the message provokes substantial controversy.

Before I go into the question of what the message ought to be and how it ought to be disseminated, I must say a word about the agency that currently referees most health claims -- FDA.

Although FDA has gone through numerous bouts of criticism, including a fair number of mine, it has always been perceived as a body devoted first and foremost to the protection of the Nation's health and safety. I have always shared and strongly endorsed this perception.

Unfortunately, we have recently seen a frenzy of second-guessing -- often for reasons based more on politics than science -- of FDA decisions by the Department of Health and Human Services (HHS) and the Office of Management and Budget (OMB).

We now have a new HHS Secretary. I hope that under his guidance this very disturbing trend will be reversed. As far as I can tell, neither industry nor consumers has favored politicizing FDA. Both want decisions made on the merits.

Also, as far as I can tell, both industry and consumers view with horror the increasing likelihood that the Gramm-Rudman bill will force huge cuts in FDA's budget. I have heard estimates of staff losses over the next few years ranging from 5 to 40 percent. If they are true, this agency will cease offering the kind of protection Americans want and deserve.

Gramm-Rudman has caused both industry and consumers to fear that the premarket approval process for drugs and medical devices, already criticized for delays, will grind to a virtual halt under the onslaught. Industry and consumers also fear that the bill will emasculate the agency's ability to halt false and misleading health claims, thereby stimulating a major quackery revival. In short, Gramm-Rudman undoubtedly presents one of the most potent threats to the Nation's health in years. Unfortunately, the time for prevention has passed. We must now work for a cure.

Finally, with respect to FDA, I would urge a modest but long overdue reform. In order to ensure greater accountability and to recognize the critical role that this agency plays, I have recently introduced a bill to require Senate confirmation of the FDA Commissioner. For those who do not know this, the head of every major federal health and safety agency — including the FAA, EPA, NHTSA and CPSC — is currently subject to Presidential appointment and Senate confirmation. The Surgeon General and the head of NIH must get Senate approval.

Everyone must except for the head of FDA. Surely, it makes no sense to exclude FDA, which has a larger budget and carries far more authority than most health and safety agencies. from the Congressional approval process.

Turning to the topic of health claims and food, although there is certainly substantial controversy, I also see a fair degree of consensus on the issue.

First, there seems to be agreement that science increasingly is demonstrating the importance of diet to health. For example, most researchers in the field seem to support the notion that Americans should move to lower fat and higher fiber diets as one way of reducing the risk of heart disease. Other links between diet and disease are being explored with increasing vigor.

In some cases, what researchers find has proven to be fairly distressing. As a member of the Human Resources Subcommittee of the House Government Operations Committee, I have been quite disturbed by a recent committee report indicating that as many as 90 percent or more of the 20,000 to 30,000 new animal drugs estimated to be on the market have not been approved by FDA as safe and effective. Moreover, according to FDA, as many as 4,000 of these new animal drugs may have "potentially significant adverse effects on animals or humans." To the extent that these drugs find their way into the our food supply, we are all at risk.

Second, most observers agree that consumers want and need truthful, non-misleading information about the health effects of the food they eat. Unfortunately, the need for information and the government's ability to deliver it seem to be heading in opposite directions. We clearly face an era of substantially reduced resources for disseminating important health information. To the extent that we can turn to the business and consumer communities to assist in informing and educating the public about healthy diets, we should do

Let me emphasize the need for truthful and non-misleading information. I forget who said that a half truth is the worst lie, but whoever did made a strong point. It does consumers no good to be told that a product is particularly nutritious if it also presents a serious hazard that the consumer is not told about. A nutritious product high in cholesterol not the same as a nutritious product low in cholesterol.

Third, we all must continue to urge FDA to attack health quackery vigorously. This is a difficult job for FDA to do when the Reagan Administration provides only lukewarm support for the agency at best and, at times, actually seems determined to <u>cripple</u> the agency's staff and authority.

Nonetheless, the battle against fraud must continue. Few things can anger a legitimate, responsible manufacturer more than to see government inaction in the face of sleazy -- and extremely profitable -- business practices. Needless to say, consumers share this view with equal intensity. I'm sure that most of you read with great interest the May 1985 issue of <u>Consumer Reports</u> in which the magazine's investigators found numerous instances of companies touting nostrums to cure everything from herpes to cancer. Obviously, not all of this quackery can be stopped overnight, but greater efforts to reduce it should be made.

Fourth, most of us agree that FDA needs to spell out with greater clarity its enforcement policy with respect to health claims for food. All of us have our notions about what such a policy should be, but the important point is that FDA ought to clarify its intentions with respect to health claims for food. We have recently seen several manufacturers extolling the virtues of their products in reducing cancer risks. Others are obviously poised to adopt a similar strategy. Before the situation develops further, FDA or the Congress should provide some guidance.

As I said, although I am not prepared to provide a comprehensive view of what our position ought to be. I do have thoughts about a couple of issues that have been raised regarding health claims for food.

Let me preface my remarks by noting, as many of you have. that there is substantial disagreement about what ought to be allowed in the advertising and labeling of food products. In particular, the Federal Trade Commission and the FDA seem to be at opposite ends of the pole. The FTC takes the position that so long as claims are substantiated, companies selling food products may make such representations about health and disease as they feel warranted. Conversely, with some limited exceptions, FDA has always taken the position that disease-related claims ought not be permitted, and, if they are made, a product should be treated as if it were a drug or device, thus requiring it to get a pre-market clearance for safety and efficacy.

My own opinion is that where there is a consensus that certain food products offer a meaningful reduction of the risk of disease it makes sense for companies to be able to note that information in their advertising and labeling. Let me hasten to add, however, that I don't think that companies should be able willy-nilly to decide which studies do and do not demonstrate the ability of a product to reduce the risk of a disease. Unfortunately, the potential for abuse is simply too great to allow that. Instead, I believe that health claims for food should be subject to some sort of validation by experts, and that we should be cautious and err—if it all—on the side of protecting the consumer.

I believe that health claims occupy a different position in the minds of many consumers than claims for, say, sporty cars or quiet washers. Because good health is so fundamental to most of us, the potential for health claims to have dramatic positive — and negative — effects is enormous. Before we encourage the dissemination of such claims, we should have a fair degree of consensus that they have merit. Unfortunately, we have seen too many recent instances of misleading and inaccurate health claims from groups that should know better. One need look only to the recent "Beef Gives Strength" and the "Coffee Lets You Calm Yourself Down" campaigns to realize that some segments of the food industry are not prepared to deal responsibly with greatly liberalized rules.

I realize that this approach might slow the promotion and thus the consumption of some food products capable of producing beneficial health effects. However, this is more than balanced by the fact that the information permitted will be substantially more reliable and credible and, accordingly, more effective.

Let me further emphasize one point I made about consensus. FDA's current policy with respect to health claims calls for scientific consensus, as opposed to mere substantiation under the FTC approach. Many manufacturers would like a reduced standard with respect to health claims.

We must proceed with caution because we have seen seen many instances of groups who, at the drop of a pin, tender volumes of studies to support any proposition they want -- no matter how contrary to accepted scientific thought. If I believed half of the "substantiated" evidence thrown at me over the years, I'd probably insist that my son take a pinch of smokeless tobacco every night after he brushes his teeth. I recall the testimony of the tobacco company researchers who claimed a great value for smoking as a way to relieve stress and the added risk stress may bring for disease.

Requiring consensus undoubtedly takes longer. But I think consensus is the right route.

In closing, I want to acknowledge and applaud the mood of this conference. A lot of the issues that we have discussed no doubt continue to stimulate debate and disagreement. But, think about the points on which there is substantial agreement. In most cases, the controversy swirls around the details — which I grant are important—rather than on the fundamentals. From what I have seen and heard, it seems quite likely that a policy acceptable to all groups can emerge if FDA is attentive and responsive to your concerns. As with all major policy matters, no one can ever be competely satisfied, but most can be adequately accommodated. We in the Congress stand ready at all times to assist you in working out a new policy. After all, it's the Nation's health that is at stake.

Thank you.